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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,410	10/03/2002	Stephane Edouard Germain	12795-009US1	3269

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03/09/2005

Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,410

Applicant(s)

GERMAIN ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-96 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 50-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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Claims 1-49 have been canceled. Claims 50-96 are currently pending and are subject to restriction.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 50-67, 77, and 81, drawn to SMAD interacting polypeptide (SIP), classified in class 530, subclass 350.
- II. Claims 68 and 69, drawn to polynucleotide encoding Smad interacting polypeptides, classified in class 536, subclass 23.1.
- III. Claims 70, drawn to antibody against Smad interacting polypeptide, classified in class 530, subclass 387.1.
- IV. Claims 71-74, drawn to method of identifying Smad interacting polypeptides (SIP) via sequence comparisons.
- V. Claims 75 and 78-80, drawn to method identifying compounds that disrupt Smad and a transcription factor via SIP, classified in class 435, subclass 7.1.
- VI. Claim 76, drawn to a compound identified by the method of Invention V.
- VII. Claims 82, drawn to method of modulating activin signaling in vitro via SIP, classified in class 435, subclass 7.1.
- VIII. Claims 82, drawn to method of modulating TGF signaling in vitro via SIP, classified in class 435, subclass 7.1.
- IX. Claims 83-85, drawn to method of modulating activin signaling in vivo via SIP, classified in class 514, subclass 2.
- X. Claims 83-85, drawn to method of modulating TGF signaling in vivo via SIP, classified in class 514, subclass 2.
- XI. Claim 86, drawn to a method of treating cancer via SIP, classified in class 514, subclass 2.

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- XII. Claim 87, drawn to a method for would repair via SIP, classified in class 514, subclass 2.
- XIII. Claim 88, drawn to a method of treating end-stage organ failure via SIP, classified in class 514, subclass 2.
- XIV. Claim 89-90, drawn to a complex of Smads, classified in class 530, subclass 350.
- XV. Claims 91, 93, and 94 drawn to a cell comprising a polynucleotide encoding a transcription factor, classified in class 435, subclass 325.
- XVI. Claims 92-94, drawn to a cell comprising a promoter for activated Smad, classified in class 435, subclass 325.
- XVII. Claims 95 and 96, drawn to a method of identifying compounds that modulate TGF dependent invasive behavior, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Upon election of an Invention, Applicants must also elect a single sequence for search. This is not a species election. The motif PP(T/N)K is a non-conserved sequence and therefore has different structure whether a Thr or and Asn are placed into the sequence. The formula at Claim 56, for example, is also not conservative, reads on thousands of sequences, and is nearly unsearchable. There is very little overlap (3 or 4 amino acids) in the sequences set forth in Claim 62, for example. Thus, while Applicants are trying to claim their invention broadly, the invention as claimed represents an improper Markush group because there is no correlation of structure and function.

If Applicants insist that all sequence be examined, Applicants must provide a single sequence to represent all sequences for search. It will be understood that if prior art is found on that sequence then all sequences claimed will be considered to be obvious variants of that sequence and rejected accordingly.

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention I are related to the antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Invention II and the antibody of Invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The polypeptide of Invention I, the polynucleotide of Invention II, and the antibody of Invention III differ in structure and function from the compound of Invention VI, the complex of Invention XIV, and the cells of Inventions XV and XVI. Therefore, Inventions I-III are patentably distinct from Inventions VI and XIV-XVI.

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Inventions I and any one of Inventions V and VII-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of the methods of Inventions V and VII-XIII.

The methods of Inventions V and VII-XIII are related in that each method requires the use of Invention I. However, the steps and end points of the methods are wholly different and therefore Inventions V and VII-XIII are patentably distinct.

The product of Inventions II, III, VI, and XIV-XVI are not used in the methods of Invention IV, V, VII-XIII, and XVII. Therefore, Inventions II, III, and VI are patentably distinct from Inventions IV, V, VII-XIII, and XVII.

The product of Invention I is not used in the method of Inventions IV or XVII and is therefore patentably distinct therefrom.

The methods of Inventions listed above require different products and steps and have different endpoints. Therefore, these Inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments**

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submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

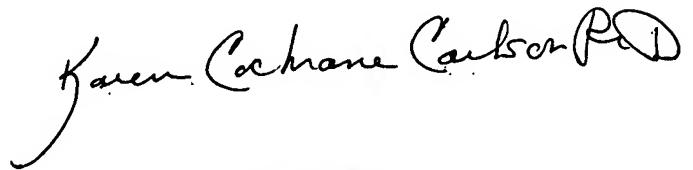
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Karen Cochrane Carlson" followed by a stylized "Ph.D." in a circle.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER